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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,627	07/29/2003	Joseph C. Maley	01307.0004U4 (ACRY4-CIP)	9066
23859	7590	12/03/2009	EXAMINER	
Ballard Spahr LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			12/03/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/630,627	<b>Applicant(s)</b> MALEY ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-17 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4,6-10 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-17 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

- Receipt is acknowledged of Applicants' amendment, response, and IDS, all filed on 23 July 2009.
- The 35 USC 112 new matter rejection of the previous Office action is withdrawn in view of the amendment and remarks.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17 and 24-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,143,794 ("Chaudhuri").

Chaudhuri discloses a topical formulation for the treatment of fungal diseases (see col. 1, lines 8-10) comprising:

- the flexible membrane of instant claims 11 and 22 (i.e. semisolid gel) (see col. 4, lines 46-47);
- the hydrophilic polymer matrix of instant claim 11 (see col. 6, lines 13-45);
- the active agent of instant claim 11 (see col. 4, line 41);
- the humectant (e.g. polyethylene glycol) of instant claim 11 (see col. 6, lines 2-12);
- the moisture content of instant claim 11, i.e. up to 68.4% (see claim 1(h));

Art Unit: 1615

- the direct contact with an ungual structure of instant claim 11 (see col. 9, lines 59-67);
- the organic acid of instant claim 11 (see col. 4, lines 22-37 – *i.e.* pharmaceutically acceptable salt of an active compound using, *e.g.* citric acid);
- the moisture management system (as disclosed in pages 23-24 of the instant specification) of instant claim 12 (see col. 6, lines 13-45);
- the attachment element (adhesive) of instant claim 13 (see col. 6, line 49);
- the polyacrylamide of instant claims 14, and 24-26 (see col. 6, line 22);
- the citric acid of instant claim 15 (see col. 4, line 34);
- the polyethylene glycol of instant claim 16 (see col. 6, lines 8-9); and
- the moisture content of instant claim 17 (see Tables D and E).

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,143,794 (“Chaudhuri”).

Chaudhuri teaches a topical formulation for the treatment of fungal diseases (see above).

Chaudhuri explains that the disclosed invention provides a gel capable of delivering an antifungal through the nail barrier (see col. 2, lines 14-15).

While Chaudhuri does not explicitly teach the percentages of instant claims 21-23, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a composition comprising a hydrophilic polymer matrix, at least one active agent, at least one humectant, and moisture content effective to create a diffusion gradient as taught by Chaudhuri. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides a gel capable of delivering an antifungal through the nail barrier, as explained by Chaudhuri (see above).

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed on 23 July 2009 have been fully considered but they are not persuasive.

Applicants' main argument with respect to the 35 USC 102 and 103 rejections of record is that Chaudhuri does not teach a flexible membrane. Examiner respectfully disagrees. It is noted that the instant specification does not provide a special definition of the term "membrane". The common definition of the term "membrane" is "a thin soft pliable sheet or layer" (see Merriam-Webster Online Dictionary entry, attached). Thus, given its broadest reasonable definition, the gel disclosed by Chaudhuri (see col. 4, line 47) reads on the newly added limitation "membrane." Since the gel disclosed by Chaudhuri is semisolid (see col. 4, line 46), it is inherently flexible.

Alternatively, the recitation "flexible membrane" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicants also argue that the instant disclosure teaches including a non-gellable polysaccharide in the antifungal composition (see remarks, page 13, second full-paragraph). However, the feature upon which applicants rely (i.e., a non-gellable polysaccharide) is not recited in the rejected claims. Although the claims are interpreted

in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, applicants use the transitional term “comprising”, which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term comprising,’ the terms containing’ and mixture’ are open-ended.”). See MPEP 2111.03.

\* \* \* \* \*

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615